WEST VIRGINIA

IN RE: TOBACCO LITIGATION CIVIL ACTION NUMBER(Medical Monitoring Cases) 00-C-6000

JUDGE ARTHUR M. RECHT JUDGE TOD J. KAUFMAN

_____/

DEPOSITION OF JIMMIE H. HARVEY, M.D.,

The telephone deposition of JIMMIE H. HARVEY, M.D. was taken before Carmen A. Velez, as Commissioner, commencing at 10:10 a.m. on August 23, 2000, by the Plaintiffs, at the Tutwiler Hotel, 2021 Park Place North, Lindberg Room, Birmingham, Alabama, pursuant to the stipulations set forth herein.

CARMEN A. VELEZ, COURT REPORTER

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No other exhibits were marked for identification, offered, or attached as exhibits hereto.

STATE OF ALABAMA, CITY OF BIRMINGHAM,
AUGUST 23, 2000,
JIMMIE H. HARVEY, M.D.,

after having been first duly sworn, was examined and testified as follows:

EXAMINATION
(via telephone)

BY MS. KLOK:

Q. Good morning, Dr. Harvey. For the record, my name is Suzanne LaFleur Klok, and I'm an attorney representing the plaintiff in this case.

A. Good morning.

Q. Would you please state and spell your name for the record?

A. Jimmie, J-i-m-m-i-e, H. Harvey, H-a-r-v-e-y.

Q. Dr. Harvey, have you ever been deposed?

A. Yes, I have.

Q. So you've been through this process before?

A. Yes, I have.

Q. Dr. Harvey, I would like to cover a few general areas regarding depositions. Do you understand that you are required to tell the truth?

A. Yes.

Q. If you do not understand a question, will you please tell me?

A. I certainly will.

Q. If you answer a question, I'm going to assume that you understand the question?

A. All right.

Q. Please try to speak audibly and don't say uh-huh, nod, or use hand gestures because the court reporter can't transcribe those.

A. All right.

Q. Also please wait for me to finish a question before answering and do not speak when I'm speaking. Additionally, I'm going to try not to interrupt your answers. But I understand this will be difficult at times, but let's try to do this so we can get through this deposition as quickly as possible. Okay?

A. I'll appreciate that.

Q. Sure. Dr. Harvey, I have a notice of deposition, which I'd like to have marked as an exhibit, and the court reporter has that. Have you seen this notice of deposition before?

A. No.

Q. All right. Attached to the back of this notice is an "Exhibit A" requesting documents from the deponent, from you, Dr. Harvey.

MR. LATHAM: Hold on, we've got to get it marked first. It's not marked yet.

THE COURT REPORTER: Now, I know Mr. Edmondson's office is still copying some, but she said these

began at the beginning. It begins with the "Notice Exhibit A"?

MR. LATHAM: We don't have a notice of deposition. We have a document that is styled on the first page "Notice Exhibit A," but we don't have a deposition notice.

MS. KLOK: Okay. Well, we'll need to get that corrected. Hold on one moment, please.

MR. LATHAM: Okay.

MS. KLOK: All right. Well, let's just continue. There is a notice, and we'll try to get that cleared up a little bit later. But attached to that notice is a Notice Exhibit A and has a schedule of documents. Do you have that document there?

MR. LATHAM: Yes, we do.

Q. Since, Dr. Harvey, it's my understanding you have not received a copy of this scheduled document?

A. That's correct.

Q. Well, I would like for you to please review this perhaps after the deposition and see if you can give to your attorney any documents that you have that may be responsive to this request.

MS. KLOK: And counsel could you forward those to me after the deposition?

MR. LATHAM: To the extent they exist, yes, we can.

MS. KLOK: Okay. Thank you very much.

Q. All right, Dr. Harvey, I'd like to take a look at your curriculum vitae.

MS. KLOK: Court reporter, do you have a copy of his CV?

THE COURT REPORTER: Yes, ma'am, I do.

MS. KLOK: Would you please mark that as an exhibit?

THE COURT REPORTER: Would you like that marked as Two?

MS. KLOK: Yes, please.

(Plaintiffs' Exhibit Number Two was marked for identification.)

Q. Dr. Harvey, is this your most recent curriculum vitae?

A. Yes, it is.

Q. Do you have any changes or modifications to this CV?

A. No.

Q. Dr. Harvey, it's correct that you are a medical doctor, correct?

A. That's correct.

Q. Where did you go to medical school?

A. Emory University School of Medicine.

Q. What year did you graduate?

A. 1977.

Q. Are you board certified in any areas?

A. Yes, in medical oncology and internal medicine.

Q. What year did you become board certified in internal medicine?
A. 1981.
Q. What did that involve?
A. It was standing for a written examination after completing the requirements of three years of accredited internal medicine residency.
Q. Do you have any requirements to keep your board certification updated annually?
A. No.
Q. What year did you become board certified in oncology?
A. 1989.
Q. And what process did you go through to become board certified in oncology?
A. It was a written examination after an accredited oncology fellowship.
Q. Do you have any annual requirements to maintain your board certification in oncology?
A. No, ma'am.
Q. Do you currently practice?
A. Yes, ma'am.
Q. Where do you practice medicine?
A. In Birmingham, Alabama, with a twelve-person oncology group and private practice.
Q. Are you affiliated with any hospitals in the Birmingham area?
A. Yes, ma'am.
Q. What are those hospitals?
A. Baptist Medical Center Montclair.
Q. Have you authured any medical books?
A. No.
Q. Have you authured any peer review publications?
A. Yes.
Q. How many?
A. Eleven.
Q. All right. Were any of those peer review publications on smoking and health?
A. No, they were not.
Q. Have you ever designed a medical monitoring program of any sort?
A. No, I have not.
Q. And I guess maybe this will -- this question may or may not be redundant, but have you authured any books or peer review publications on the subject of medical monitoring?
A. No, I have not.
Q. Have you ever been a consultant to the Surgeon General's office on any Surgeon General's reports on smoking and health?
A. No, I've not.
Q. Are you familiar with the term "peer review" as it's used in the context of medical and scientific publications?
A. Yes, I am.
Q. What does peer review mean?
A. In the context of, that I'm familiar, it is the submission and review of data and research material by thought leaders and

members that are of a specific profession who have some expertise in that area. And my concept of it is that before information is published in journals, that others within the field review that with an unbiased view towards the information, try to render it acceptable or unacceptable.

Q. Why is it important to have a peer review process in your opinion?

A. Well, I think without peer review there's a lot of science that, although it is noble in cause, really doesn't stand the test of examination from outside -- that the person doing the research.

Q. Have you met with any attorneys in preparation for your deposition?

A. Yes, I have.

Q. Which attorneys?

A. Mr. Wattleworth and Mr. Latham.

Q. When did you meet with them?

A. I met with them -- Mr. Wattleworth, on three occasions; and the first time in June, a second time in July, and just early this week.

Q. And then you met with another attorney?

A. Mr. Latham was with Mr. Wattleworth this past week.

Q. And you just met with Mr. Latham on one occasion this past week?

A. That's correct.

Q. Were there any nonlawyers present when you met with those attorneys?

A. No.

Q. Have you met with any attorneys regarding your expert disclosure in this case? Well, I guess you should say --

MS. KLOK: Well, we can mark as an exhibit your "Expert Witness Disclosure of Jimmie Harvey." Would you please do that?

MR. LATHAM: All right. We'll find it.

MS. KLOK: Okay. Great.

THE COURT REPORTER: We also have the "Notice of Deposition," ma'am, that was just brought to us, so I can mark that Number One if you'd like.

MS. KLOK: Yes, please. Thank you.

(Plaintiffs' Exhibit Number One and Exhibit Number Three were marked for identification.)

Q. Dr. Harvey, did you meet with any --

MR. LATHAM: Hold on. We've got an expert disclosure for Dr. Harvey, I think not for this case. It's not clear from the document which case it applies to.

MS. KLOK: Well, this was produced to the plaintiff as linkage to the medical monitoring case as Dr. Harvey's expert witness disclosure. It did not have a

heading on it. It came as a part of a group of documents.

MR. LATHAM: All right. I'm not arguing with you, we're just checking it out.

MS. KLOK: Sure. I understand. But, no, it doesn't have "In Re: Tobacco Medical Monitoring Cases."

MR. LATHAM: Okay. We've got it.

Q. Dr. Harvey, do you have this expert witness disclosure of Jimmie H. Harvey in front --

A. Yes.

Q. -- of you marked as Exhibit Three?

A. Yes.

Q. Have you seen this document before today?

A. Yes.

Q. My question then is: Did you meet with any lawyers in the course of preparing this expert disclosure?

A. Not -- no, ma'am.

Q. Okay. Did you prepare this expert disclosure yourself?

A. No, I did not.

Q. Who prepared this disclosure?

A. Mr. Wattleworth.

Q. Did you review this expert disclosure with Mr. Wattleworth?

A. Yes, I did.

Q. Do you believe -- we've established now that you're familiar with this expert disclosure; is that correct?

A. Yes.

Q. After having seen this expert disclosure, do you agree with the opinion set forth in this disclosure?

A. Yes.

Q. Do you have any changes or modifications you'd like to make to this expert disclosure?

A. No.

Q. You said you've been deposed before. Have you been deposed in any tobacco-related cases before today?

A. No, ma'am.

Q. What are your current rates for consulting?

A. Three hundred and fifty dollars an hour.

Q. How many hours have you consulted for the tobacco companies in this case?

A. Approximately twenty-four hours.

Q. When did the cigarette companies first contact you to be an expert?

A. In either late May or early June of this year.

Q. Do you recall who you spoke with?

A. Mr. Wattleworth.

Q. Did anyone mention where they got your name? Do you know how they came in contact with you?

A. Actually I think it was through -- Mr. Wattleworth had gone to law school in Birmingham and a mutual friend of ours, who I believe he had worked with during the summer, Mr. Tom Christian, a lawyer here in

town, had I think just suggested that he contact me.

Q. Sure. Okay. You mentioned that you've been deposed in other litigation. What type of litigation was that?

A. One is in a malpractice suit, and the second time as the treating physician in an asbestosis case.

Q. In that asbestosis case, were you retained by the defendants or the plaintiffs, do you recall?

A. I think -- it was a little unclear because I was the treating doctor --

Q. I see. I'm sorry. I thought --

A. -- so I was deposed by both sides.

Q. Now for your medical malpractice case, were you a party in that case?

A. Unfortunately, yes.

Q. As a defendant?

A. As a defendant.

Q. Dr. Harvey, do you have any materials on which you rely for your opinions that are set forth in your expert disclosure?

MR. LATHAM: Object to the form of the question.

Q. Dr. Harvey, did you review any scientific medical journals before you prepared or reviewed this expert witness disclosure?

A. Yes, I did.

Q. What are those articles?

A. I have a list that I presented and can present to you. It's a lengthy list of articles related to lung cancer diagnosis, screening, previous work in the field, several textbooks, and I depend upon, really, the Internet for reviewing literature as well, but I do have a set of documents that I, in particular, reviewed.

Q. And do you have hard copies of those documents or just a list?

A. I have hard copies.

MS. KLOK: Counsel, plaintiffs request a copy of those documents.

MR. LATHAM: All right. We'll take that under advisement.

Q. Did the lawyers provide you any medical, scientific medical articles for you to review?

A. Yes, they did.

Q. Do you recall what articles those were?

A. There is probably seven or eight and the -- in our initial meeting, they provided me with -- the article in particular I remember is the Henschke article from The Lancet and then a follow-up article from The Lancet a year later. And then there's several general articles about screening, and I can't recall exactly the list, but I've actually listed those and can provide those to you.

Q. So when you provide the list to us, you can show or mark which articles the defendants

provided to you?
A. Certainly.
Q. Thank you. Do you have any of those articles with you today?
A. No, I don't.
Q. Dr. Harvey, are you a cigarette smoker?
A. I'm not.
Q. Were you ever a cigarette smoker?
A. No, ma'am.
Q. In your opinion, does cigarette smoking cause disease?
A. Yes.
Q. Which diseases?
A. Cigarette smoking is associated with lung cancer, chronic obstructive lung disease or COPD, emphysema, cancers of the upper airways; the head and neck. It's been associated with bladder cancer, been associated as a co-factor in heart disease and in peripheral vascular disease.
Q. Doctor, is a person who has a history of smoking cigarettes at a significantly increased risk of contracting latent -- serious latent diseases above a person who does not have a history of smoking cigarettes?
MR. LATHAM: Object to the form of question. It's vague, but you can answer.
Q. You can answer.
A. Certainly I agree it's a health risk to smoke cigarettes.
Q. On what do you base that opinion?
A. I've been practicing medicine for a little over twenty years now, and it's an opinion I base on my experiences.
Q. Have you reviewed any pleadings in the Blakenship case that's also entitled "In Re: Tobacco Litigation, Medical Monitoring"?
A. What's a pleading?
Q. If you saw the document, it would have at the top "In The Circuit Court of Ohio, West Virginia," and, for example -- have you reviewed the complaint in this case?
A. No, I have not.
Q. Have you reviewed Dr. Burn's expert report in this case?
A. Yes, I have.
Q. Which expert report? There are three. Have you reviewed the revised expert report dated, I believe, February 2000?
A. I don't know if it was revised when it's -- it's the one that was provided to me.
Q. Do you have a copy of that expert report?
A. In my person, no. I do have a copy of that.
Q. Would that be in your file --
A. Yes.
Q. -- that you would keep on this case?
A. Yes, ma'am.
Q. Again, plaintiffs have requested that if you could provide us with a copy of that file after this deposition.
A. Yes, ma'am.

Q. Is it your opinion that all cigarettes are unreasonably dangerous when used as directed by the manufacturers?

MR. LATHAM: Object to the form of the question, calls for legal conclusions. Subject to that, you can answer the question.

A. To be honest with you, I really don't have an opinion regarding that.

Q. Do you agree that addiction to tobacco is stronger that heroin addiction?

MR. LATHAM: Object to the form of the question.

A. I disagree with that.

MS. KLOK: From the court reporter, I'd like for you to give Dr. Harvey a copy of the Baptist Health System brochure.

THE COURT REPORTER: Would you like that marked as Number Four?

MS. KLOK: Yes, please.

(Plaintiffs' Exhibit Number Four was marked for identification.)

Q. Dr. Harvey, have you seen this brochure before today?

A. No.

Q. Would you look on the second page?

A. All right.

Q. Where they state, "You can quit anytime you want to. Isn't it about time you took control?"

A. Yes.

Q. Do you see the statement, "Addiction to tobacco is stronger than heroin addiction"?

A. Yes, ma'am.

Q. Is it true that Baptist Health Care System is affiliated with the Baptist Medical Center in Montclair?

A. It is.

Q. What is that relationship?

A. They're really one and the same.

Q. Okay. Is it just a -- one goes by that name but it's --

A. Well there's a -- I'm sorry to interrupt you. There's, I believe, eleven hospitals in the system.

Q. Okay. And the Montclair hospital center is just one of those hospitals?

A. That's correct.

Q. Is it your opinion that cigarette smoking causes eighty-five to ninety percent of the lung cancer that occurs in the United States?

MR. LATHAM: Object the form of the question, lacks foundation.

A. I'd agree it's yes.

Q. On what do you base that opinion?

A. Again, my experiences as an oncologist now for seventeen years and a doctor for over twenty years.

MS. KLOK: Court reporter, I'd like to mark for the next exhibit the 1989 Surgeon General's Report.

THE COURT REPORTER: That will be marked as Number Five.
(Plaintiffs' Exhibit Number Five was marked for identification.)

Q. Dr. Harvey, are you familiar with the 1989 Surgeon General's Report?
A. Only in concept. I've not read it.
Q. Do you disagree or agree with the statement that "Smoking is responsible for an estimated thirty percent of all smoking deaths, including eighty-seven percent of lung cancer, the leading cause of smoking mortality"?
MR. LATHAM: Object to the form of the question. It's vague and lacks foundation.
A. I don't have a firm opinion regarding that.
Q. Okay. When you evaluate a specific person or patient, would you determine what risk factors exist for that patient?
A. Yes, I would.
Q. If a risk factor exists, isn't it true that a risk factor needs to be considered in the process of reaching a diagnosis and determining a treatment, if any?
A. Yes.
Q. Do you agree that a person that smokes is at an increased risk for certain diseases?
A. Yes.
Q. Just because there are multiple risk factors that doesn't change the fact that smoking is still a risk factor, does it?
A. No.
Q. Do you have know or have any idea under what circumstances a person who smokes would not be at an increased risk?
A. Would you ask that again?
Q. Sure. Under what circumstances would a person who smokes not be at an increased risk?
A. I would imagine using what we know about time and dose exposure that someone who had smoked a cigarette a day for the last two or three years might be considered a very low risk for any disease related to that or someone who had quit smoking fifty years ago. I mean, I can make up scenarios, but I think the question, to me, is more a dose relationship, and that's what I'm looking for when working with people who have cancer?
Q. Okay. Does a smoker with a five-pack year history have an increased risk of contracting cancer?
A. It's a slight increase compared to someone who has never smoked.
Q. Doctor, assume for this question that an individual has no other risk factors other than a five-pack year smoking history. Would you agree that they have an increased risk of contracting lung cancer?
A. Yes.
Q. Would you agree that smoking is a risk

factor for lung cancer?
A. Yes.
Q. Do you agree that before a medical monitoring program can be set up, a person must have some exposure to a known risk factor?
A. Yes.
Q. Have you reviewed any of the medical records of any of the individual class representatives in this case?
A. No, I have not.
Q. Dr. Harvey, how many patients do you see daily?
A. Between thirty-five and forty-five.
Q. Are all those patients lung cancer patients?
A. No, they're not.
Q. Could you just explain to me what type of patients you see in your practice?
A. I see adult patients with all solid tumors, except gynecologic malignancies and adult patients with hemologic malignancies, such as, lymphoma, and leukemia. And I also in my practice see adult patients with benign hematologic problems; anemia, low blood platelets, and other benign blood disorders.
Q. Do you have any idea of a percentage of your practice that is related to lung cancers?
A. It's in the range of thirty percent.
Q. Of that percentage, how many of those are smokers in your practice?
A. Sixty-five percent approximately. That's a guess, but I'd say around that number.

MS. KLOK: For the court reporter, would you please mark a "Guide to Clinical Preventive Services" as the next exhibit?

(Plaintiffs' Exhibit Number Six was marked for identification.)

Q. Dr. Harvey, would you please turn to page XLI? I'm sorry, I don't know what the Roman numeral is.
A. Okay.
Q. The second paragraph starts -- and I'm going to read this out to you and then ask you some questions.
A. Okay.
Q. "The second criterion for selecting preventive services for review was that the maneuver had to be performed in the clinical setting. Only those preventive services that would be carried out by clinicians in the context of routine health care were examined. Findings should not be extrapolated to preventive interventions performed in other settings. Screen tests are evaluated in terms of their effectiveness when performed during clinical encounter. Screening tests performed solely at schools, work sites, health fairs, and other community locations are generally outside the scope of this report. Also, preventive interventions implemented outside the clinical setting, e.g., health and

safety legislation, mandatory screening, community health promotion, are not specifically evaluated, although clinicians can play an important role in promoting such programs and encouraging the participation of their patients. References to these types of interventions are made occasionally in sections of this book."

Are you familiar with this "Guide To Clinical Preventive Services"?

A. No, I'm not.

Q. Let's take this line by line. The sentence that states "The second criterion for selecting preventive services for review was that the maneuver had to be performed in a clinical setting," do you agree that this statement means that the methodology examined was limited to only those performed in a clinical setting?

MR. LATHAM: Object to the form of the question, lacks foundation. He's already testified that he hasn't reviewed this extensively to comment on specific sentences, but subject to that I'll let him answer the question.

A. I've got to be honest with you I'm not sure what you're asking, but do you want to ask again?

Q. Sure. Do you agree that this statement means that the methodology examined was limited to only those performed in a clinical setting?

MR. LATHAM: Same objection.

A. It says it had to be, but that's what it says. I agree that's what it says.

Q. Do you acknowledge that the author's limited his report to only those preventive services that would be carried out by clinicians in the context of routine health care were examined?

A. That's, you know, in the context of reading one paragraph out of a book I -- that just says what it says. I agree that's what I'm reading.

Q. Okay.

A. I really don't understand the context of what they're talking about, but that's --

Q. Do you understand that in this case the plaintiffs are asking the court to set up a medical monitoring program?

A. Yes.

Q. Do you understand as part of the plaintiffs' proposed medical monitoring program, plaintiffs are asking that certain tests or evaluations, or medical tests be performed on class members to meet the criteria of the class definition he follows in the guidelines for receiving such testing?

A. Yes.

Q. Do you have any information that leads you to believe that the test Dr. Burns is recommending could only be carried out by

clinicians in the context of routine health care?

A. Ask that again. I mean, I'm just a little confused about what --

MR. LATHAM: You're talking pretty fast. It's hard to hear you sometimes.

Q. Okay. I'll slow down. Sorry about that. Do you have any information that leads you to believe that the test Dr. Burns are recommending could be carried out by clinicians -- that could only be carried out by clinicians in the context of routine health care?

MR. LATHAM: Object to the form of the question. It's vague. Dr. Burns has proposed lots and lots of tests in many different forums. Which test are you referring to? That might help him answer the question.

Q. Okay. Well, why don't we take them -- the EKG testing?

A. The EKG testing?

Q. Yes. Page forty.

MR. LATHAM: What's the question?

Q. The question is: Do you have any information that leads you to believe that the EKG testing that Dr. Burns recommends at age forty could only be carried out by clinicians in the context of routine health care?

MR. LATHAM: The question is still vague and confusing. Subject to that, he can answer.

A. You can do an EKG about anywhere you'd like. You can do it in a shopping mall. You don't have to be at a doctor's office to have that done, if that's the question.

Q. Okay. What if the -- same question as respect to spirometry?

A. Again, that can be done at your health fair or your shopping mall, and it is done outside of clinical settings.

Q. What about chest x-ray?

A. Same answer. That can be done, you know, really anywhere, and it is done outside of clinical settings.

Q. What about sputum cytology test?

A. Again, that can be done basically anywhere.

Q. What about CT scanning, spiral CT scanning?

A. That requires -- well, it gets still -- and there's now the availability of doing that really anywhere. It doesn't require a clinical setting or a doctor.

Q. What about PET scanning?

A. I'm so unfamiliar with PET scanning, I think that could not be done anywhere except in a clinical setting.

Q. Okay. The authors in this document state that the "Findings should not be extrapolated to preventive interventions performed in other settings." Do you have

any basis to agree or disagree with this statement?
A. No, I don't.
Q. Do you have any basis to disagree with the authors' statement that "Screening tests are evaluated in terms of their effectiveness when performed during the clinical encounter"?
A. No.
Q. Do you acknowledge that the authors' limit the scope of this report to "Screening tests performed solely at schools, work sites, health fairs, and other community locations are generally outside the scope of this report"?
MR. LATHAM: Object to the form of the question. It's vague.
A. That's what it says.
Q. Okay. Do you acknowledge the authors also limit the scope of this report in that they state, "Preventive interventions implemented outside the clinical setting are not specifically evaluated, although clinicians can play an important role in promoting such programs and encouraging the participation of their patients"?
A. Again, that's what it says.
Q. Okay. Are you aware in this case that the Court will ultimately determine what sort of medical monitoring program would be provided to the class members, if any?
A. Yes.
Q. In your opinion, would a medical monitoring program ever be beneficial in any circumstances?
MR. LATHAM: Object to the form of the question. It's overbroad and vague.
Q. If you can answer.
A. I would, you know, as an oncologist and someone who takes care of cancer patients, you know, it's a -- I would certainly hope that we can find a monitoring or screening test that would be effective for all cancers.
Q. Have you ever recommended a medical monitoring program for any individual?
A. No.
Q. Have you ever recommended a medical monitoring program for a population?
A. No.
Q. In your expert disclosure you state that you are, quote, "Expected to testify that plaintiffs' proposed medical monitoring program should not be adopted and is not medically or reasonably necessary." Are you commenting on all aspects of plaintiffs' proposed medical monitoring programs?
MR. LATHAM: Object to the form of the question. It's vague. I'm not even sure anybody knows what your proposed monitoring program is. Subject to that, you can

answer the question.
A. Well, the only -- in this case, what I've seen in terms of the proposal involved spiral CT scanning and, I believe, actually -- and this is probably in the last couple of weeks -- involved PET scanning. And as a practicing physician and as a scientist, I applaud the effort to find a screening test that works, and I'm still waiting and expectantly and hopefully that there will be one. I just don't believe we have them yet.
Q. Is it fair to say, Doctor, that you will not be commenting on the use of EKG for diagnosis of heart disease in the context of plaintiffs' proposed medical monitoring program?
A. That's correct.
Q. It's also fair to say the same of the exercise stress test proposed for diagnosis of heart disease?
A. Yes, ma'am.
Q. Is that fair to say for spirometry?
MR. LATHAM: Say that again.
A. Spirometry?
Q. Spirometry.
A. That's true. And I would not comment on that.
Q. Is that the same for spitum (sic) cytology?
MR. LATHAM: Sputum.
A. Sputum. Yes, ma'am. I'm sorry.
MR. LATHAM: Repeat the whole question again. I think it's not clear what you're asking.
MS. KLOK: Okay. The court reporter, could you please read back my first question?
MR. LATHAM: The one about sputum cytology?
MS. KLOK: No. Regarding about EKG.
THE COURT REPORTER: Yeah. It shouldn't be too far back.
MS. KLOK: Well, that's okay.
Q. Doctor, what I'm asking is I'm just trying to determine the parameters of your testimony of what you're going to be offering in this case. My question about sputum cytology is: Will you be commenting or testifying in this case about plaintiffs' proposed medical monitoring program as it relates to sputum cytology for the diagnosis of lung cancer?
A. Yes, I will.
Q. Will you be doing the same for chest x-rays?
A. Yes, I will.
Q. Will you be doing the same for spiral CT?
A. Yes, I will.
Q. Will you be doing the same for PET scanning?
A. Yes, I will.
Q. Do you know what the criteria is for breast screening?
MR. LATHAM: Object to the form of the question. What do you mean by

breast screening?
MS. KLOK: Breast cancer screening.
I apologize.
A. Yes.
Q. What is that criteria?
A. Well, the one that I adhere to is the American Cancer Society consensus that all women at the age of forty should begin annual mammographic examinations, along with self-breast exam and clinical exam by a physician. There is -- and I believe that all women should have that for the rest of their life.
Q. Do you believe that women over fifty have to -- I'm sorry, over forty have to be evaluated by their physicians before they can receive a mammography and a breast cancer screening program?
A. I believe that's appropriate, but I also believe that if mammography is made available to those in a more convenient setting, and they're people who would otherwise not get one because they just don't see doctors, I would not object to that.
Q. Are you familiar with the recommendations for screening teachers and health care workers for tuberculosis?
A. Yes.
Q. Are you aware that such screening takes place in the United States?
A. Yes.
Q. Is it your opinion that prior to any tuberculosis screening that a teacher or health care worker wouldn't have to be evaluated by a physician?
A. I'm not familiar with that.
Q. Okay. Are you familiar with the recommendations for vision screening for children?
A. I should be, but I'm not.
Q. In your expert witness disclosure you state that you, quote, "Will testify that it is recognized that early detection of tumors is important in effecting disease outcome and people developing prostate, breast, cervix, skin, testicle, and colon rectum cancer." On what do you base your opinion?
A. My previous training and continued medical education since training and my personal experience as an oncologist.
Q. What is the scientific evidence that you're using to support this screening of at-risk patients for prostate cancer?
A. Well, again it's the same as before; my knowledge based on readings and my experience. Although I think there's a great deal of controversy in that, in screening for prostate cancer.
Q. Do you have any particular articles, medical journal articles that you could point me to that would support that screening for prostate cancer?

A. Off the top of my head I would refer you to the DeVaita Textbook on oncology, which sort of is a compendium and my basic source book.
Q. Okay. What is the scientific evidence that you rely on to support the screening of at-risk patients for breast cancer?
A. Again, my general knowledge of breast cancer, my experience over the last seventeen years acknowledge that breast cancer screening is an effective tool for decreasing the mortality of that disease?
Q. Are there any scientific medical articles you could point me to on that issue?
A. Again, I would go to the DeVaita Textbook, which probably on screening for breast cancer would have a hundred articles referenced. So I couldn't name a specific article.
Q. What is the scientific evidence that you use to support the screening of at-risk patients for cervix cancer?
A. Again, I'd have to go to the general textbook and then get specific references. I couldn't quote a specific reference off the top of my head.
Q. What is the scientific evidence that you use to support the screening of at-risk patients for skin cancers?
A. It would be the same answer. I would -- I'm in such a broad field that I don't remember any specific article, but I'd go to DeVaita if I was looking for one for you or you wanted to find one.
Q. Okay. Would your answer be the same for testicle cancer?
A. Yes.
Q. Would it be the same for colon rectum cancer?
A. Yes.
Q. In forming your opinion as reflected in your expert disclosure regarding plaintiffs' proposed medical monitoring program, did you utilize any sort of decision-making model?
A. No.

MS. KLOK: The court reporter, would you please mark as the next exhibit "Common Screening Test by David Eddy"?

THE COURT REPORTER: Yes, ma'am. That will be Number Seven.

(Plaintiffs' Exhibit Number Seven was marked for identification.)

Q. Dr. Harvey, are you familiar with this article by Dr. David Eddy?
A. I'm not.
Q. Would you please turn to page seven of the Eddy article?
A. All right.
Q. All right. In this article Dr. Eddy notes that evidence, direct evidence, directly connecting the application of a screening test with the occurrence of health outcomes is very rare. Do you have any basis to

disagree with this statement?
A. Where?
MR. LATHAM: Where are you reading that from?
Q. The last paragraph on -- it's titled "Direct Evidence."
A. Okay.
Q. And the last sentence says, "Unfortunately, this type of evidence is rare, usually because huge numbers of people must be screened to generate a sufficient number of outcomes for statistical analysis, and because many of the outcomes are chronic and require long follow-up time."
MR. LATHAM: I'm going to object at this point. Dr. Harvey hasn't had a chance to read this entire document. I think to ask him what one sentence out of a paragraph is is unfair. And I'd like him to have the opportunity to read the entire document that you've given him before he answers these questions.
Q. Well, Dr. Harvey, you know, with understanding the objection, would you be able to answer this question, notwithstanding the objection?
A. Well, unfortunately, ma'am, it should take --
MR. LATHAM: Hold on. If he wants to read the document, he's entitled to it; and if he doesn't want to read it, he doesn't have to. But I'm going to give him the opportunity before he answers any questions.
Q. Okay. Dr. Harvey, would you like to read the document now?
A. No.
Q. Okay.
A. I mean, a quote on a sentence out of a fairly lengthy article, I'm not sure what the context is. I'm not being, you know, obtuse with you. It's just -- if I gave you one sentence out of a big document and asked you to comment on it, I don't think you'd be comfortable.
Q. Fair enough. Dr. Harvey, you mentioned that you practice medicine at Baptist, I believe it's Memorial Montclair?
A. Right.
Q. Do you practice medicine at any other facilities?
A. Yes, ma'am.
Q. Where are those facilities?
A. Well, I have rounding -- I do rounding covering my partners at Baptist Medical Center Princeton, Bessemer Carraway Medical Center.
Q. Could you please spell that Bessemer?
A. B-e-s-s-e-m-e-r; Carraway, C-a-r-r-a-w-a-y.
Q. Okay. Any other facilities?

A. No.
Q. At Baptist Medical Center Montclair is it a standard policy to not order medical tests if they are not covered by insurance?
A. No.
Q. The same question for Baptist Medical Center -- is that Princeton?
A. Princeton.
Q. Princeton.
A. No.
Q. What about the Bessemer Carraway?
A. No.
Q. Does lack of insurance constrain ordering tests?
A. Is that a general question for me or --
Q. Yes, a general question for you.
A. In a very broad brush it does, but in the hospitals I work at, anybody that I think needs a test, I've been able to work out. I've never had to not do a test because of insurance or a payment issue. But, yes, it is very constricting occasionally and requires a lot of -- if it's something that I deem necessary, it can take some work to get it done.
Q. Does Baptist Medical Center Montclair have a standard practice on tests to order on smokers who are asymptomatic?
A. No.
Q. Does Baptist Medical Center Princeton have a standard practice on tests to order on smokers who are asymptomatic?
A. No.
Q. Same for Bessemer Carraway?
A. No.
Q. Have you ever recommended an x-ray for an asymptomatic smoker?
A. Yes.
Q. In what context?
A. Someone with fevers, productive cough, someone I might suspect pneumonia.
Q. On how many occasions have you done that if you can quantify?
A. That'd be impossible. I've been practicing for almost twenty-one years.
Q. Okay. Have you ever had an asymptomatic smoker come into your office and request a chest x-ray?
A. No.
Q. Do you see asymptomatic smokers in your office in your practice?
A. Yes.
Q. Why are those asymptomatic smokers there? Do they have other health care concerns?
A. They would have other malignancies.
Q. Other malignancies?
A. Yes.
Q. Do you see patients who do not appear to have any problems -- you're not a primary care physician, really is my question?
A. No, ma'am, I don't see primary care patients.
Q. So in your practice you don't really seek

people who don't believe they're sick for any reason?

A. Correct.

Q. Have you ever seen a patient with an abnormality that you made a diagnosis of lung cancer?

A. Yes.

Q. What would the staging of that like a -- do you recall how many patients where that occurred?

A. Again, that would be extremely difficult to quantify. I'd have no way to quantify it after this many years of practice.

Q. Have you ever seen a patient with a spiral CT scan that had abnormalities or changes where you made a diagnosis of lung cancer?

A. No.

Q. Same question as to PET scan?

A. I'm sorry. Now start over again with PET scan. Have I ever --

Q. Yeah. Have you ever seen a patient with a PET scan that showed abnormalities or changes where you made a diagnosis of lung cancer?

A. I've seen a patient with a PET scan -- well, the context I've been -- I've only used PET scan for about two months is I've sent patients with lung cancer for a staging to see how extensive the lung cancer was. That's my context of use of PET scan, and that's in two occasions.

Q. Have you used spiral CT scanning in your practice to diagnosis lung cancer?

A. No.

Q. In what context -- have you ever used spiral CT scanning?

A. You know, in retrospect, my radiologist tells me that I have, but it's been in the context of regular use of CT scanning. I didn't realize that I was using spiral CT.

Q. Were the results of the CT scanning used to assist you in making a diagnosis of lung cancer?

A. No.

Q. Well, in what context was the CT scan used by your radiologist with your patients? I'm just confused by that, if you would explain.

A. To be honest with you I'm not an expert in radiology, and so the difference between our spiral CT scanner or our normal CT scanner is on most tests that we do is of no consequence to me as a clinician. So I think when we had the capacity several years ago, and we had several CT scanners at our hospital, some people were getting spiral CTs, and I didn't realize that was any different than a regular CT at that time.

Q. So you've had patients who have had a spiral CT scanning and you've used the results of that scan to diagnosis lung cancer?

MR. LATHAM: Object to the form of the question.

A. Not that I know of, not for diagnosis, no.

I'm not really on the diagnostic end of lung cancer business. I see patients who have lung cancer who have already been diagnosed.

Q. So you're not -- you wouldn't consider yourself an expert in diagnosis of lung cancer?

A. Yes, I would. I believe my training and my certification both imply that, and I'm proud to say that I believe I am an expert in diagnosis of cancer and treatment of cancer of all adult --

Q. I'm sorry, Doctor. I was just confused by the answer to your previous question.

A. Well, I'm not an expert in radiology, and, you know, understand the general principles of helical or spiral CT versus regular CT, but in a very vague sense. I understand how jet airplanes work, but I couldn't fly one. I depend on the experts in radiology to help me utilize those tests and interpret them.

Q. So a radiologist would assist you in interpreting the results of a scan --

A. Yes.

Q. -- to make a diagnosis for lung cancer?

A. If I was making the diagnosis of lung cancer. But, as I said, I treat patients who already have lung cancer.

Q. So you generally -- in your practice is it fair to say that patients who arrive at your door have already been diagnosed with lung cancer?

A. Yes, ma'am.

Q. Do you see patients that have not been diagnosed with any lung cancer but are sent to you for diagnosis of lung cancer?

A. That's not the general way that it works.

Q. So your practice consists of -- again, and I apologize for restating. I just want to be clear. It consists of patients who have already been diagnosed with lung cancer, and you're their treating oncologist?

A. Correct.

Q. Thank you.

MR. LATHAM: Can we take a short five minute break?

MS. KLOK: Sure.

(A short break was taken.)

MR. LATHAM: All right. We're back. We can go back on the record.

Q. (BY MS. KLOK) Dr. Harvey, did you discuss this deposition during the break?

A. No. And actually I just forgot. Can we take one more minute?

Q. Sure.

A. I walked out and went to the bathroom and forgot to make a phone call that I need to make. It will just take about two seconds.

Q. No problem.

(A short break was taken.)

MR. LATHAM: We can go back on the record.

EXAMINATION CONTINUED

Q. (BY MS. KLOK) Dr. Harvey, before we broke

again, did you -- I asked did you discuss this deposition during your break?

A. Only he said that you talked very fast and if I didn't understand, to slow down, but we didn't discuss the deposition per se.

Q. Did you discuss the case at all?

A. No.

Q. In general, can cure rates for lung cancer be different for different stages of diagnosis?

MR. LATHAM: Object to the form of the question.

A. I think in a broad sense, cure rates have a lot to do with such a heterogenous group of factors, such as; the type of tumor and the ability to treat it. Some tumors are more treatable; the growth rate of the tumor, the time in a person's life when the tumor is found in terms of other core morbidus (sic). Cure -- to use the word "cure" by stage, I think, is pretty oblique and difficult to pin down.

Q. Can cure rates for lung cancer differ depending on the stage at which a disease is diagnosed for, say, a squamous cell carcinoma? Would that make a difference by identifying the type of cancer?

A. That could be one of many important factors in curability of a cancer, of a lung cancer.

Q. In your expert witness disclosure, you state, "That proponents of lung cancer screening in asymptomatic populations, especially helical CT scan screening, advocate that early detection yields lower stage tumors and improved probability of intervention that is potentially curable." On what information do you base this statement?

A. Reading the papers given me regarding the planned screening.

Q. And what papers were given to you?

A. It was the -- it's the proposal, the actual proposal of the plaintiffs' for a screening program.

Q. Okay. In your expert witness disclosure you state, "That previous studies show no change in death rate despite a threefold increase in early stage tumors among screened individuals." On what do you base your opinion?

A. In the past twenty years there's been a number of studies. And off the top of my head, probably the most important one was the Mayo Clinic study involving chest x-ray and sputum cytology, which although it picked up earlier cancers than in those who were not screened -- I'm taking historical data -- there was unfortunately no change in the overall morbidity of the disease.

Q. What other studies to you reference besides the Mayo Clinic study?

A. Off the top of my head I don't remember the names of the studies, but there's been at

least three large studies that are commonly known and cited for screening for lung cancer.

Q. Are you referring to one of the Sloan-Kettering Institute studies?

A. Maybe I don't remember if that's exactly the one.

Q. Or the Johns Hopkins study?

A. That certainly could be one of them as well.

Q. Do you expect that if a resectable tumor is found, that the five-year survival rate is fifty to seventy percent?

A. I'm sorry. Would you repeat that, please?

Q. Do you expect that if a resectable tumor is found in a lung cancer patient that the five-year survival rate is fifty to seventy percent?

A. I really have no reason to believe that is to be true, and my experience is probably a little contrary to that.

Q. What is the survival rate in your opinion?

A. It depends on the -- you'd have to break it down to what tumor type it is, the location, and now with the, you know, with better staging, including micromolecular staging, I think there's just so many factors. I can't honestly give an opinion as to what the cure rate is, and I'm not sure. And certainly I would think that at five years -- I don't tell people they're cured of cancer after five years, after their surgery.

Q. Well, maybe perhaps I misspoke. What I meant to ask was if that a -- do you expect that if a resectable tumor is found that the five-year survival rate is fifty to seventy percent?

MR. LATHAM: Object to the form. It's really hard to hear because you're talking really fast.

Q. Okay. Do you expect that if a resectable tumor is found that the five-year survival rate is fifty to seventy percent?

MR. LATHAM: Object to the form of the question, asked and answered, same question.

A. Again, I think that's a generalization that I -- if you ask me if a certain size squamous cell carcinoma peripherally found in a -- I mean, and break it down, I might be able to get some sort of a general guess, but I don't have an opinion as to the curability because I think that's -- lung cancer is so heterogenous.

Q. Okay. So you're saying to me -- is it correct for me to state that you can't give a general overall five-year survival rate for lung cancer?

A. I don't think anyone can, but no I cannot.

Q. Okay. So because of that opinion, would you be able to answer that whether or not if a nonresectable tumor is found that the survival rate is fifteen percent?

A. Well, again you're, you know -- you're

talking about just lung cancer, in general, is such a broad and heterogenous group. I wouldn't -- I'm asked this all the time: What are my chances? And I think that's a very difficult -- to come up with except in an individual, you know, with the tumor location, the type of tumor, and I believe the treatments are changing now. And I believe there's what we call a lead-time factor where people are being diagnosed earlier and living longer, but still dying of the disease. So five years sort of becomes a -- everybody talks about five years, but I think that's not really a good standard anymore of measuring death rates.

Q. So if a patient came to you and asked you if, say, they had a resectable tumor and they asked you what are my chances of surviving after five years, what would you tell them?

A. If a patient came, an individual patient, I would try to offer them as much hope as possible and tell them we were going to do everything we could to help them achieve the longest survival they can, but that it was really difficult to give them an idea what their curability rate was.

Q. Would you give them a number?

A. Never.

Q. In your expert witness disclosure you state that, "A recent study of smaller tumors by helical CT scanning failed to show a relationship between tumor size at the time of discovery and survival." What study are you referring to?

A. It's reported in the Journal Chest this year. It was a study from the group at Duke University.

Q. Okay. Who was the author?

A. I forget -- the leader author was Patz, I believe. But one of the authors was Dr. David Harpole, a thoracic surgeon there that I'm familiar with?

Q. How did this study come to your attention?

A. I refer patients to Dr. Harpole and I've been a colleague of his now for about three or four years. We've talked about it, and when it was finally published he just told me that it was being published.

Q. Is this study a retrospective or a prospective study?

A. It was really more of an analysis. I think they -- and that is a retrospective study by the strict definition.

Q. Did the study throw out patients whose tumor grew over a certain size?

MR. LATHAM: Did you say "throw out"?

Q. Yeah. Disregard. Yeah. Throw out patients whose tumors grew?

A. No. And I say that with all certainly I don't remember the exact, but I don't believe there was an exclusion criteria. I'd have to look at the methodology of the

article. Again, I've not analyzed it completely or to that degree to have it committed to memory.

Q. Did this study address resectability?

A. Yes.

Q. In what way, could you tell me, please?

A. Well, they have criteria, and I couldn't tell you the exact criteria, but their reason to be is to resect lung cancers among the thoracic surgery group, and so they sought to the utmost of their skill and with their preoperative screening to resect everyone that was possible to resect.

Q. Did this study include patients with a sustained sized tumors, but some of those tumors were in the advanced stage?

MR. LATHAM: Object to the form of the question. It's confusing.

A. This group of patients, it was a diverse group, but those in this study were all deemed to be early or resectable tumors. So in terms of the stage there may have been some variation in the early stages between a stage one or a stage two, but these were all considered resectable tumors.

Q. Were any of the tumors -- were any of the patients found to have advanced spread of cancer even though they had only small tumors?

A. I'm sure there was some patients who had unexpected metastatic disease, but it would be the minority. I don't recall the exact number, but that's always the case; just total surprise metastatic disease. But the ones who went to operation went there without any preoperative evidence that they were going to have disease anywhere else.

Q. In your expert disclosure you state that "While admirable to advocate lung cancer screening, there remains no scientific evidence to support its application to high-risk persons." On what do you base your opinion?

A. Well, as an oncologist with seventeen years of experience and one who follows this closely, and I look to the American Cancer Society, the National Institutes of Health, the National Cancer Institute, my governing and educational body of the American Society of Clinical Oncology, all of whom have what I consider the ability to put together thought leaders and to critically look at this whole issue. None of these groups, all of whom have a vested interest in finding screening that would work, have been able -- have advocated a screening test yet for lung cancer. And I do, I say it's admirable, because I wish there was a screening test that was effective. And in my practice, I depend on these organizations and I depend on my expertise and my ability to look at this information.

Q. In your expert witness disclosure you state

that "The application of plaintiffs' proposed screening program at this time to the general population at risk goes against all scientific principles that physicians hold paramount." What are those scientific principles that you refer to?

A. Well, I think the application of a therapy or a diagnostic test, there are certain standards to which we apply. And for screening we apply a very simple test, but it's one generally -- it's not generally, it's accepted uniformly that a screening test when given to a population at risk for a disease should have an impact on the disease, and in the case of cancer should impact on mortality and death rates from lung cancer.

Q. Is it fair to say that your objection to the screening techniques is on the basis that these screening techniques, in your opinion, have not proved that they decreased mortality rate --

A. Could you repeat that?

MR. LATHAM: Is there a question? We didn't get the end of it.

Q. Yeah. I'm asking is it fair to say that it's your opinion that these screening techniques for lung cancer should not be adopted because they have not, in your opinion, been shown to decrease mortality rates?

MR. LATHAM: Object to the form of the question. You can answer.

A. That's correct.

Q. In your expert witness disclosure you state that "The general application of unproved tests, therapies, or procedures is not the standard of care." How do you define unproved tests?

A. I think -- I believe that's sort of self-explanatory in that a test that has not been shown to be effective at what it's supposed to be doing is unproven.

Q. And what is the method that is used to prove or disprove a test? Is it a randomized trial that you -- are you referring to a randomized trial?

A. In this situation of screening, I believe a randomized test is the accepted standard to which a screening test, a diagnostic screening test, would have had to be held.

Q. So is it fair to say that it's your opinion that a test -- to determine whether a test is proved or unproved it must go through a randomized trial?

A. Yes.

Q. In your expert witness disclosure you state that you will, quote, "Testify that there is no evidence at this time that would allow it to become a screening tool for lung cancer." And do you mean spiral CT scanning?

A. What this -- I would say that about spiral CT scanning and all other modalities which

have been looked at up to this point have unfortunately -- and I again emphasize I don't want to sound like I don't want to diagnose cancer, but unfortunately have not been shown to be effective in effecting the mortality rate from lung cancer. So I would include chest x-ray, sputum cytometry -- I mean cytology, helical CT scanning, and PET scanning.

Q. And on what do you base your opinion?

A. My knowledge of the detection programs up to this point and my experience in clinical oncology and the recommendations of the American Cancer Society, the American Society of Clinical Oncology.

Q. Has the American Cancer Society or any of those other societies commented on PET scanning?

A. No, not that I know of.

Q. Have they commented on spiral CT scanning?

A. Yes, they have.

Q. In your opinion, what is their position on spiral CT scanning, the American Cancer Society?

A. I think, like me, they recognize that it's a tool that needs to be evaluated, and they recognize that we currently don't have a good screening, and that the testing needs to be done on any potentially helpful diagnostic tool because it would certainly be nice to have a screening tool to have in lung cancer. But they do not recommend right now any screening for lung cancer.

Q. Has the American Cancer Society, in your opinion, or do you know if the American Cancer Society has stated anywhere that spiral CT scanning should not be used for screening of lung cancer?

A. I'm only aware that the current position of the American Cancer Society in which their annual report says that right now they can recommend no standardized screening for lung cancer in high-risk persons. Does that answer your --

Q. And where -- I'm sorry. I apologize for interrupting.

A. That's all right.

MR. LATHAM: Did you finish your answer?

THE WITNESS: Yeah, I'm finished.

Q. Where would I find that? What annual report are you referring to; is that 2000?

A. It'd be the year 2000. I believe it comes out in either early December, early January each year, and it's in a journal form.

Q. Are there any other organizations where you would say that they have said spiral CT scanning should not be used for lung cancer screening?

A. I'm not aware of the actual saying spiral CT should not be used. I'm only aware that the organizations that I would look to for help in trying to determine if something was

appropriate -- which is my organization the American College of Radiology, the American Cancer Society -- all as recently as this year 2000 do not have a recommendation or state that there is no current screening for lung cancer.

Q. Have they commented on spiral CT in particular?

A. I can't address each and every one of them because I think in, such as, the American Society of Clinical Oncology has addressed spiral CT as it has chest x-ray, sputum cytology, some other fluoroscopic-aided bronchoscopy, many, many things that are out there that are hopeful, but none have been proven to be successful by our measures of what a screening test should do.

Q. So the American College of Oncology have they stated a position on spiral CT scanning? I thought that's what I heard you say, and I may be wrong.

A. No. And I didn't say that. Because I don't think the American Society of Clinical Oncology is making statements about therapies or diagnostics. But we have had symposia at our annual meeting where we address the issues of screening and the consensus at the symposium was that there still is no screening for lung cancer.

Q. Dr. Harvey, if you look at the population of individuals who've contracted lung cancer, do you agree or disagree that eighty percent of lung cancers occur in smokers?

MR. LATHAM: What did you say that eighty percent "occur." Is that the word you used?

MS. KLOK: Occur.

Q. Yeah. Eighty percent of lung cancer occur in smokers?

A. I'm not -- no, I wouldn't think it's that high. And, again, lung cancer is sort of -- it's very -- let me just say it another way. I see a number of patients with lung cancer who never smoke and I think that's generally accepted that it occurs, and I see a number of patients who have cancers which are thought to be lung cancer and clinically are lung cancer, but now with the better techniques we find that in point of fact are probably not lung cancer but represent metastatic disease from other places because that's a common site of metastatic disease. The eighty percent number, I would generally say, that's probably not the case in my experience, and I think in general all lung cancers probably not be -- would probably not be true.

Q. Do you agree or disagree that the incidence of lung cancer begins to climb rapidly at age forty and increases dramatically between ages forty and eighty?

A. I would -- just on a pure age, I think the relation of age is more -- it would be by

itself rather meaningless. It's more how much exposure to tobacco is where the risk factors are. And the risk factor really climbs at -- people have the equivalent of a pack per day for twenty years is where the risk begins to climb, I think. The break point where the statistics start mounting and the risks -- or the -- yeah, the really -- incidence of lung cancer takes off is somewhere on the north side of fifty years of age.

Q. And what do you base your opinion?

A. My general medical knowledge of lung cancer.

MS. KLOK: Will the court reporter -- I'd like to mark as the next exhibit an article entitled "Early Detection in Lung Cancer, Case Findings and Screenings."

THE COURT REPORTER: That will be Number Eight.

(Plaintiffs' Exhibit Number Eight was marked for identification.)

Q. Dr. Harvey, are you familiar with this article?

MR. LATHAM: Let him have a chance to look at it first.

MS. KLOK: Sure.

A. Yeah, I'm familiar with this article.

Q. Would you first turn to page sixty-five?

A. Sixty-five?

Q. Yeah, page sixty-five.

A. All right.

Q. It's under the title "Populations At Risk" paragraph two, "Age," states, "Although difficult to separate out from smoking and a variety of other environmental factors, the incidence of lung cancer begins to climb rapidly at age forty and increases dramatically between ages forty and eighty."

A. All right.

Q. Do you disagree with this statement in light of your previous answer where you stated that it begins at age fifty in your opinion?

A. Well, I mean, I think this covers that where it says, "Increases dramatically between the ages forty and eighty," and I believe that mid-fifty range would fall under that forty and eighty. Personally, I see very few -- and again personally I see very few lung cancer really under the age of fifty. The vast majority that I see is over the age of sixty.

Q. Apart from who you see actually in your practice, do you agree or disagree with that statement that I read previously?

A. I agree within the general sense because it has that it increases dramatically between the ages of forty and eighty. So, specifically, I have no problem with that area because in that forty years between forty and eighty, that's when it does increase.

Q. Okay. Thank you. Do you know what

percentage of the diagnosed lung cancers in the United States last year were operable?
A. Not off the top of my head.
Q. Okay. So would you know what percentage of the diagnosis of squamous cell carcinoma of the lung diagnosed last year in the United States was operable?
A. Again, not off the top of my head.
Q. The same for an adenocarcinoma of the lung?
A. Same.
Q. As for oat cell or small cell carcinoma of the lung?
A. Again same answer.
Q. Do you know what percentage of diagnosed lung cancers in the United States last year were resectable as opposed to operable?
A. A little unclear of that -- what's -- of your --
Q. Of last year that were resectable then?
A. Were resectable? Again, I don't know off the top of my head what and -- I don't know that right now.
Q. With respect to squamous cell carcinoma?
A. I don't know that figure off the top of my head.
Q. What about adenocarcinomas of the lung?
A. Again, same answer.
Q. What about diagnosis of small cell or oat cell carcinomas of the lung?
A. Same answer.
Q. Doctor, isn't it true that the only curative treatment for lung cancer is resection at an early stage of the disease?
MR. LATHAM: Did you say the word curative?
MS. KLOK: Yes.
A. Well, you have to keep in mind I'm a medical oncologist, so I can cure some cancers with chemotherapy as well, and I believe my radiation therapy colleagues feel they cure some patients with radiation therapy. So I don't believe it's the only curative.
Q. In your opinion can early detection of lung cancer and intervening with treatments elongate a patient's life?
A. It's a fairly general -- I think, all the interventions that we try and do as physicians, as radiations therapist, thoracic surgeons and oncologists hope to at least offer a quality of life and hopefully a -- some quantitative benefit. And that being said, I believe that all the interventions for lung cancer have that potential, and that's why we do what we do.
Q. Do you believe that surgery, chemotherapy, radiation treatment, et cetera, results in better outcomes for lung cancer patients as opposed to do nothing for those patients?
MR. LATHAM: Object to the form of the question.
A. Well, it depends on -- I mean, again, that's such a complex -- you're asking about -- unfortunately from what we know about

resection of early disease, we're not impacting on the ultimate result of lung cancer, which is death. And chemotherapy, despite the fact that I do that every day, has not changed the death rates and neither has radiation therapy. I think for me the issues are more a quality of life, but unfortunately we're not impacting on mortality.

Q. So just so I'm sure. Is it your opinion that surgery will not increase survival for lung cancer patients as opposed to doing nothing for that patient?

MR. LATHAM: Object to the form of the question.

A. I don't think we live in a society where that information will ever be made available because I don't believe you're going to be able to not operate on operable patients. But unfortunately -- and there are studies to bear this out that biology is more important than the surgery for lung cancer in that we know that we're resecting and we look back at people found early, twenty-five years ago found with early lung cancer do not have an improvement in their death rate compared to those that are found at a much later and symptomatic time of their disease.

Q. Would your answer be the same for chemotherapy?

A. Embarrassingly, yes.

Q. What about for radiation treatment?

A. Absolutely, yes.

Q. Do you agree that while prior to the late 1990s early diagnosis has not been shown to improve long-term survival at this time and, therefore, major medical groups do not currently recommend screening for the detection of lung cancer?

A. Am I aware of that?

Q. Do you agree with that statement?

A. Yes.

Q. Are you aware that these recommendations are currently being reconsidered in light of advances in early detection of lung cancer using newer radiological and molecular biological techniques?

MR. LATHAM: Object to the form of the question. It's vague.

A. I think there is a whole industry of medical scientists looking for screening for not only lung cancer but a number of other malignancies.

Q. Then I'll ask my question in this way: Are you aware that these recommendations are currently being reconsidered in light of advances in early detection of lung cancer using CT screening?

MR. LATHAM: Object to the form of the question. It's still vague. Who? Who's reconsidering it?

Q. If you can answer, Doctor.

A. Am I aware --

MR. WATTLEWORTH: Do you need her to repeat the question?
THE WITNESS: Yeah.

A. Could you repeat that?
I mean, I think in my document marked Exhibit Three, I believe I outlined that, and I just said that there are a number of people, and I'm sure people are looking at every one of the modalities which are new and more current than x-ray therapy are looking at all those. So I'm sure they're out there, yes.

MS. KLOK: The court reporter, I'd like to mark as the next exhibit the "International Conference on Prevention and Early Diagnosis of Lung Cancer, 1988."
THE COURT REPORTER: All right. That's Number Nine. Go ahead.
(Plaintiffs' Exhibit Number Nine was marked for identification.)

Q. Dr. Harvey, did you attend this conference?
A. No, I did not.
Q. Are you aware that in light of the recommendations that the International Conference of Early Diagnosis of Prevention and early Diagnosis of Lung Cancer is looking to modify those recommendations because of the advances in CT scanning?
MR. LATHAM: Object to the form of the question, lacks foundation.
A. I'm familiar with that.
MS. KLOK: Court reporter, I'd like to mark the next exhibit "Early Lung Cancer Action Project: overall design and findings from baseline screening, by Claudia Henschke."
(Plaintiffs' Exhibit Number Ten was marked for identification.)
Q. Dr. Harvey, are you familiar with this study?
A. Yes, I am.
Q. Is this the study that you reference in your expert witness disclosure?
A. I believe it is.
Q. Are you aware of the study that the preliminary evaluation of the utility of spiral CT scanning suggests that the potential to detect as many as eighty percent of lung cancers at a stage where they are surgically curable?
MR. LATHAM: Is that a question?
MS. KLOK: Yes.
A. As it's stated, I think I'm not sure that's the claim in terms of curability. I think you can find early lung lesions with helical CT, and I believe this particular project shows that very dramatically that you can find abnormalities that are very small on a chest CAT scan.
Q. Dr. Harvey, would you please turn to page one-o-three?
A. All right.

Q. In the second column the third paragraph, the second full paragraph that begins, "We have not yet followed up all our participants with malignant disease to determine cure."

A. All right.

Q. I'll just read the paragraph and I'll ask you questions if that's okay. "We estimated five-year survival of sixty percent for these baseline cases from the stage-specific five-year survival rate (sic) of the Mountain. This estimate is conservative because it does not take into account the much smaller size of the stage 1A tumors in our study or the much higher five-year survival of eight-five to a hundred percent reporting for such small tumors. If we take ninety percent as the five-year survival for stage 1A tumors, our overall estimate increases to eighty percent. These estimates of survival are consistent with those reported for CT screening by the National Cancer Institute in Japan."

My question, Doctor, is do you agree or disagree to the statement that, "If we take ninety percent of the five-year survival for stage 1A tumors our overall estimate increases to eighty percent"?

A. I'm not an expert at statistics, but I'm aware of reading this type of data and there is a fault that I believe even Dr. Henschke agrees to that finding early tumors, especially peripheral early lung cancers creates a terrible bias that's still felt at five years. A bias towards what's known as lead-time bias that at five years a lot of these patients may not experience the recurrence in the death rate that they will experience at a later date, at six, seven, eight, nine, ten more years. And unfortunatily this same type of data is what led the excitement early in the chest x-ray screening, but that data unfortunately because of the lead-time bias when you follow these patients more than five years, it fell apart in chest x-rays. And that's not to say it's going to fall apart in this data, but I believe it very difficult, treacherous, and not sound to base a curability on five year for these very early lesions. Five-year survival is not a cure for this particular lesion.

Q. Would you define what lead-time bias is in your opinion?

A. Well, if you, in front of you, draw a line on a piece of paper and put a hash mark at the far left end and a hash mark at the far right end and that is the biologic behavior of a -- and we'll say in this case lung cancer, or you could say with breast cancer -- and no matter, and it is certainly we know with -- a lot of people die with very early stage breast cancer,

unfortunately. If you diagnose a person who was biologically going to have metastatic disease and end up dying at the right side hash mark, if you diagnosis them very far to the left, towards that left hash mark, and you do any intervention, you find it at that point or do any intervention, you're going to show a survival benefit compared to if you find them a little further to the right on that hash mark. So that lead-time bias is where you might think that an intervention -- and we talk about it a lot in therapies, but an intervention appears to have benefit when it really doesn't. It was just that you just bought some extra time. You discovered things a little earlier on that time line. And that's a general, sort of graphic, definition of lead time or lead-time bias.

Q. In your expert witness disclosure it states you are, quote, "Expected to testify that the study of early lung cancer action project initiated 1993 evaluating the usefulness of helical CT scanning was a single cohort recruiting study and had no comparison arm."

Doctor, are you referring to the Claudia Henschke study in that statement?

A. Yes.

Q. Would you please explain what a single cohort recruiting study is?

A. It's an evaluation of a selected population, where they either receive a -- in the general sense, in what I do, where they receive a therapy, but there is no comparator to know if the therapy has improved the outcome. In this case, the screening was done without a comparator to know if you really have effected the outcome.

Q. So is that what you refer to as a comparison arm; the comparator?

A. Correct.

Q. And what would compare the study -- the group to?

A. In what context?

Q. In the context of that study.

A. Well, this study would had to be compared with those who are allowed to go about normal, expected medical follow-up and not involving, in this case, helical CT scanning?

Q. Why do you criticize the Henschke study as being, you know -- for that reason, for the single cohort recruiting study that had no comparison arm?

A. Well, without a comparison arm, you have no idea if you've impacted on the mortality disease because there's just so many other factors that lead to morbidity and lung cancer. I mean, I think it's an accepted standard of scientific endeavor in basically all fields of science, and in particular in

the human sciences; that type of study is what validates and proves a concept.

Q. So would it be your opinion that she would -- that you would need to have a randomized trial study in order to validate CT scanning?

A. Yes.

Q. In your expert witness disclosure it states you will, "Further testify that, while encouraging, the study does not, nor was it designed to, test the ultimate goal of a screening test-reductions of mortality in a defined at-risk population." On what do you base this opinion?

A. Would you repeat that again, please?

Q. Sure. In your expert witness disclosure it states, "You will further testify that, while encouraging, the study does not, nor was it designed to, test the ultimate goal of a screening test-reduction of mortality in a defined at-risk population." On what do you base this opinion?

A. Well this is a -- this does not prove that. This is a single arm; there's no comparison. So we don't know what the reduction is in this. It's subjective and really doesn't take into account the whole disease itself. This is an exciting first step and it's to be applauded, but it's not an applicable science yet.

Q. Is it your opinion that the only way to determine if a test reduces mortality in a defined at-risk population is to have a randomized trial?

A. Yes.

MS. KLOK: I'd like to mark the next exhibit, please, the "First International Conference on Screening for Lung Cancer."

(Plaintiffs' Exhibit Number Eleven was marked for identification.)

Q. Dr. Harvey, are you aware that in response to this challenge on this, you know, screening for lung cancer at the First International Conference on Lung Cancer Screening was held in October 1999 that included a group of international experts on imaging, molecular diagnostics pulmonology, oncology, epidemiology, et cetera, to address the issues central to lung cancer screening?

A. Yes.

Q. Did you attend this conference?

A. No, I did not.

Q. Were you invited to this conference?

A. No.

Q. Are you aware of the findings of this conference?

A. Vaguely.

Q. Are you aware that this meeting was cosponsored by the American Cancer Society, The National Cancer Institute, ALCASE, Weill Medical College of Cornell University and

other organizations?
A. Yes.
Q. Are you aware that "The conference reviewed the currently available data on lung cancer screening and engaged in intensive analyses of the implications with a view to attaining a consensus with respect to the main issues surrounding the early detection of lung cancer"?
MR. LATHAM: Object to the form of the question, lacks foundation.
A. Yeah. I'm not totally attuned to exactly what the objectives and what all went on. I've read reports from the meetings and, you know, are aware of the findings of the meetings.
Q. Are you aware that it was agreed at this meeting that subsequent to the institutional policy statements not recommending screening for lung cancer that two important developments occurred?
MR. LATHAM: Object to the form of the question, lacks foundation.
A. I'm really not aware of that.
Q. Okay. Are you aware that at this meeting they determined there was compelling evidence to emerge over the past decade that resection of early lung cancer has a major bearing on survival?
MR. LATHAM: Same objection.
A. No, I'm not aware of that.
Q. Are you aware that this conference determined that new techniques now provide for distinctly early detection of the disease of lung cancer?
A. Again, I'm not familiar with that specific issue.
Q. If you take those conclusions as correct, does it follow that modern screening for lung cancer would save lives?
A. I really couldn't make that opinion. It would require review of all the information. It's pretty subjective.
Q. This exhibit that we marked for "The First International Conference on Screening for Lung Cancer," dated 1999, have you seen this summary before?
A. No, I have not.
Q. But you are aware of the general findings of the conference?
A. Yes, I am.
Q. What are you aware of those -- in your opinion, what were the findings of that conference?
A. I believe it was a -- the information that was there was a number of reports, but the one I'm most familiar with was the Henschke report and the -- and I'm aware there was a number of discussions there regarding going forward with a program to look at helical CT scanning in a randomized perspective fashion. That it, you know, was agreed I think, generally agreed, that it's exciting.

It needs to be studied.
Q. You stated that it needs to go forward in a randomized trial. Where do you -- can you pinpoint to me where that's written or I can find that stated at that conference?
A. No, I really couldn't.
Q. Do you know at that conference that they discussed randomized trials for spiral CT scanning?
A. Yeah. I really don't know exactly all the things they discussed there. No, I don't.
Q. Okay. I'm just confused because I thought I heard you state that they said that a randomized trial for CT scanning should take place. I just want to find out where I can find that recommendation.
MR. LATHAM: Object to the form of the question. It's vague.
A. Well I'm not, you know -- I think to be clear, I did not state that. I would assume that if we had a bunch of scientists there involved with lung cancer screening and they have a promising test, it would be really a knee-jerk reaction -- not a knee jerk. I think everyone would say: Well, gosh, let's get a randomized trial, and let's do it quickly. So that's an assumption. I don't know that. I was not at that meeting and I suspect -- and this supposition -- I imagine a lot of things went on at that meeting in the hallways, in the coffee gatherings where people discussed a lot of issues. But I would imagine that since it's a formidable group of scientists and scientific groups, that a lot of issues regarding screening were discussed. But I wasn't there; I'm not privy to any of that.
Q. Your expert witness disclosure states that you will "Testify that lung cancer screening of high-risk populations has been evaluated, and in randomized controlled trials failed to show a reduction in mortality in the screened groups as compared to controlled, nonscreened groups." On what do you base your opinion?
A. On my general knowledge of the field and my experience as a practicing oncologist.
Q. Which studies do you reference?
A. In particular I would, off the top of my head, reference the Mayo Clinic study.
MS. KLOK: The court reporter, I'd like to mark the next exhibit "Screening for Lung Cancer, Another Look; A Different View by Dr. Strauss."
(Plaintiffs' Exhibit Number Twelve was marked for identification.)
Q. Dr. Harvey, have you read this article?
A. I believe I have.
Q. Are you aware that the authors note that the "Mayo Lung Project, the Memorial Sloan-Kettering Lung Project, and the Johns Hopkins Lung Project support the conclusion

that cure rates in lung cancer would be more than double if population-based periodic chest radiographic screening were carried out"?

MR. LATHAM: Object to the form of the question. Where are you reading from?

Q. If you'll look at page seven sixty-six, the first column, the fourth full paragraph, the first line.

A. (Witness complies.)

Q. Dr. Harvey?

A. Yes.

Q. Do you agree or disagree with this conclusion?

A. You know I -- based on what I know, I would probably disagree. And I'd like, you know -- I would certainly like to read this more thoroughly. But whenever I read this, it sort of takes in something I've mentioned before that treatment is different, but I would also think that this article -- I'm not sure when it was published now, in 1997 -- probably is not even quite as up-to-date in the overall assessment of some of these projects. But I think this is a controversial statement, and I wouldn't agree with it.

Q. Okay. Dr. Harvey, in the same article on page 766, the last paragraph, it states "In summary and in conclusion, annual chest x-ray screening favorably influences stage distribution, resectability, survival, and fatality in lung cancer." Do you agree or disagree with Dr. Strauss?

A. I really don't have -- and again not having looked at that, I would say that I, at face, would have disagreement with them on a number of issues with this.

Q. And what are those issues?

A. Well, I think a number in terms of I would argue that there's evidence in these studies that show there is no change in the mortality despite early diagnosis. And I would fast-forward him to 1999 and 2000 where there's now equally compelling data, in particular, the Patz and Harpole data, and the review now of the Mayo Clinic data at twenty-five years which shows there is no difference. So I would agree, and I think it would be a collegial disagreement.

Q. The study that you just referenced is that in a list of reference materials that you would agree to provide for me?

A. Yes, ma'am.

Q. Okay. Have you ever conducted a study related to the effectiveness of screening for lung cancer?

MR. LATHAM: What was the word; successiveness?

MS. KLOK: Effectiveness.

MR. LATHAM: Effectiveness?

MS. KLOK: Effectiveness.

A. No, I have not.
Q. Do you agree that forty percent of lung cancers can be detected on an x-ray in stage one of the disease?
A. I think that's a -- I don't think I could agree to that. I'm not really clear in my mind and clear in my knowledge of the literature that that's the exact percentage that are found at that stage. There's too many -- there's just a lot of variables in that that make it hard to say what percent everything is found at just by pure x-ray, because that's not the only way people are diagnosed.
Q. Do you agree that seventy to eighty percent of resected stage one lung cancer results in long-term survival?
A. I disagree.
Q. What is the basis for your disagreement?
A. The two primary reasons are my personal experience backed up by what I had suspected for many years, and what I think a lot of people suspected, but also the recent data from the Duke University group and also the reassessment of the Mayo Clinic Early Lung Cancer finding group.

MS. KLOK: I'd like to mark for the next exhibit "Screening for Lung Cancer; The Mayo Lung Project Revisited."

THE COURT REPORTER: Yes, ma'am. That will be Number Thirteen.

(Plaintiffs' Exhibit Number Thirteen was marked for identification.)

Q. Dr. Harvey, are you familiar with the study?
A. You know, I'm really not. I'm not familiar with this.
Q. So you haven't read it before?
A. No.
Q. Could you turn to page 1579?
A. All right.
Q. I'm going to read a paragraph under the conclusion, it's the third paragraph. "Simulation of a program of thirty-five years, from age forty-five to eighty, of annual radiographic examinations for lung cancer indicates at most a modest decrease in lung cancer mortality compared with no screening at all; however, we point out that even a ten percent reduction in death from lung cancer in the United States would save fourteen thousand lives annually, which is comparable to or greater than the total number of deaths from carcinoma of the stomach, ovary, or bladder, or tumors of the central nervous system." Are the authors stating that there is a decrease in cancer mortality with screening?
A. I have not read this. I'm not exactly sure of what they're saying because they're talking about a simulation of a program. To be honest with you, I'm not sure what they mean by that. I think what they're doing

is -- and I'm guessing -- that a simulation is an extrapolation of this population to a more general population which -- again, not being a statistician, but being very familiar with how statistics can be worked -- that's a leap of faith. But, again, I want to say just for this particular article that I'm not sure what a simulation is, other than maybe an extrapolation.

Q. But taking into account your assumptions of what they mean, would you say that you disagree with that conclusion?

A. Well, I'm not sure how they made the assumption. So, yeah, I would disagree based on I don't know how they made the assumption and it's just not a very, to me, very factual assumption.

Q. Okay.

MS. KLOK: And the court reporter, I'd like to mark the next exhibit "A randomized study of chest x-ray screening for lung cancer as part of the Prostate, Lung, Colorectal, and Ovarian Trial."

THE COURT REPORTER: That will be Number Fourteen.

(Plaintiffs' Exhibit Number Fourteen was marked for identification.)

Q. Dr. Harvey, are you familiar with this article?

A. I'm not.

Q. Are you familiar with any article that critiques the Mayo Clinic Lung Project?

A. That critique the Mayo Project?

Q. Yeah.

A. I'm sure there are many, and I've seen some.

(After brief interruption, the following was had:)

Q. Some. Dr. Harvey, I believe you stated you're familiar with some studies that critique the Mayo Lung Project. Are any of those studies listed in your materials?

A. Yeah. I would say that there probably are, either in editorial form or letters. I think any article that I have about lung cancer screening will have critiques of the Mayo Clinic study and other studies.

Q. Would you look to the first page wherein this author states that "One problem in the Mayo Lung Project was contamination in the control group," the last paragraph?

A. Correct.

Q. "Investigators estimated that about fifty percent of the subjects in the control group had chest x-rays outside of the study, often because of pulmonary complaints common in smokers." Do you disagree or agree with this criticism?

A. I have no feeling one way or the other about it.

Q. Okay. Could you look to the first paragraph where it -- I'm sorry, it would be the

second paragraph -- where it reads "Early lung cancer screening trial in the 1950s and '60s were for the most part uncontrolled and nonrandomized and therefore, of inadequate design to make a statement of benefit regarding screening. These included the Philadelphia Pulmonary and Neoplasm Research Project, the Veterans Administration Study, the South London Cancer Study." Are you familiar with this criticism?

A. Yes.

Q. Do you agree or disagree with that criticism?

A. I agree.

Q. What is your basis to agree? Why do you agree with that criticism?

A. Well, I think nonrandomized, uncontrolled studies are just not to be used for the basis of determination of the benefit or lack of benefit for a method.

Q. In your expert witness disclosure, you state that you will "Testify that the NCI has proposed a randomized controlled trial comparing chest x-ray to helical CT scanning and at-risk persons and that such studies are needed to validate a screening test for application to the general population." Where did you get your information regarding their proposed NCI randomized trial?

A. From the National Cancer Institute.

Q. Is it written anywhere that NCI has proposed a randomized trial?

A. Yeah. They issue bulletins. They've had several bulletins regarding the proposal for a trial and the design of the trial.

Q. Do you have copies of those bulletins?

A. Yes, I do.

Q. Are those in the list of materials that you are going to provide me?

A. Yes.

Q. In your expert witness disclosure, you state that you will testify that another trial is being proposed by the American College of Radiology Imaging Network to see if screening with helical CT scanning reduces lung cancer mortality." Where did you get your information regarding the proposed American College of Radiology Imaging Network proposed randomized trial?

A. That was in the NCI information.

Q. Was it in the same bulletin as the NCI information?

A. It may have been. There have been several bulletins. But it's -- it may have been both in the same or maybe in a separate one advocating other trials.

Q. Would these bulletins be in your list of materials that you have agreed to provide me?

A. Yes, they will.

Q. And is that the only place that I would find that information on the proposed randomized trial?

A. Well, I think in the information I'll provide you there's several articles this year based on some symposium and some evaluations of -- you know, reevaluations and critiques of earlier studies that I believe mention or make note of the NCI trial and other trials that I believe are going to be going forward.
Q. So that NCI trial and the American College of Radiology Imaging Network those are both proposed randomized trials comparing chest x-rays to helical CT scanning?
A. I don't know the exact design. I think the designs are still being worked on it. So it's a trial that's being formulated right now as we speak.
Q. But both of those trials deal with the helical CT scanning for at-risk persons to diagnose lung cancer?
A. I can't say for absolute that that's going to be. It may end being some other kind of test, but I know that's what was in the literature I've read.
Q. So that those proposed randomized are dealing with looking to see whether or not helical CT scanning reduces lung cancer mortality?
A. Correct.
Q. In your expert witness disclosure you state you "May be asked to comment upon the opinions expressed by other witnesses and/or any additional evidence developed for and during trial to the extent that they relate to your area of expertise." Have you been asked to comment on the opinions expressed by other witnesses?
A. No, I have not.
Q. Have you been asked to comment upon any additional evidence developed before trial to the extent they relate to your area of expertise?
A. I haven't seen anything or been asked to yet.
Q. Dr. Harvey, the textbook that you talked about earlier, the oncology textbook that you referred me to if I wanted to find different scientific articles regarding breast cancer screening and other screening, what is the title of that textbook?
A. I believe it's just called Oncology.
Q. Okay. Is that listed in your listed materials?
A. I'll list it for you.
Q. Okay. I'd appreciate that.
A. Okay.

MS. KLOK: I don't have any other questions unless co-counsel does?
UNKNOWN COUNSEL: No questions.
THE COURT REPORTER: Who is that, sir?
MR. LATHAM: Who just spoke? We might want to have appearances for the record, because I don't know if the court reporter got everybody

that's on the line, so we might want to go ahead and do that now.

I think I have a couple of questions just to follow up, but I want to take two minutes to confer with counsel here.

MR. KAMARADAS: That was John Kamaradas from Goldberg, Persky, Jennings & White.

MS. CROOKS: Susan Crooks of Womble, Carlyle, Sandridge & Rice.

MR. FLEIHMAN: Travis Fleihman of Jackson & Kelly in Charleston, West Virginia, on behalf of Brown & Williamson.

MS. HARVEY: Rhonda Harvey with Bowles, Rice, McDavid, Graff & Love, in Charleston, West Virginia, local counsel for R. J. Reynolds.

MR. WAJERT: Sean Wajert, Dechert, Price & Rhoads for Philip Morris.

MS. KLOK: Suzanne Klok with Ness, Motley, Loadholt, Richardson & Poole in Charleston, South Carolina.

THE COURT REPORTER: Go ahead.

(No response.)

THE COURT REPORTER: I take it that's everybody?

(A short break was taken.)

MR. LATHAM: Does anybody else on the phone have any questions?

(No response.)

EXAMINATION

BY MR. LATHAM:

Q. All right. I have a couple of follow-up questions. For the record, my name is Will Latham from the Womble, Carlyle firm. I represent R. J. Reynolds.

Dr. Harvey, you were asked some questions about smoking and lung cancer, and my question is: Is there any medical test that you as an oncologist can perform to establish definitively the cause of a person's lung cancer?

A. No. In the terms of actually testing a tumor or testing a person, there isn't a -- it's a subjective correlation of a number of factors which would lead you to make a presumption. But there's no definitive test; there's no way to say absolutely.

Q. When you use the term "cause" and the term "risk factor," do you use those two terms interchangeably?

A. I think a lot of times, you know, I might in conversation, but in terms of causing cancers versus risk factor I think there is a definitional difference, and not splitting hairs like what is, is, but risk factors are exactly that: They're components that might involve increasing the risk of something happening. It's not an absolute. I always

use the -- with patients the correlation -- not the correlation, but the example that a lot of people smoke, but really a relatively small number of people get lung cancer. So it's a risk factor, but it's not a guarantee that it will cause the cancer.

Q. You were asked some questions about the percentage of lung cancer cases in the U. S., and I have forgotten the exact question, but it had to do with eighty-five to ninety percent of the lung cancers in the U. S. Have you done any sort of analysis for this case to assess what proportion of those cancers were caused or not caused by smoking?

A. No.

Q. You were asked some questions about duration of smoking and what duration of smoking creates a significant risk for lung cancer, and I'm a little unclear as to whether or not you believe the epidemiology supports that a five-pack year history or a twenty-pack year history creates an increased risk for lung cancer?

A. Well, I think the data would back up the exposure phenomenon of twenty-pack years and that sort of correlates also with the age in that you don't see many twenty-five, thirty year olds. So I think the real break point and we can argue about is that forty-eight versus fifty-two, but the break point in terms of exposure is twenty-pack years is where the dramatic increase and the rate of cancer development occurs.

MR. LATHAM: I don't have anymore questions.

MS. KLOK: I have a couple of questions.

FURTHER EXAMINATION

BY MS. KLOK:

Q. Is there a difference between a prevalence of the incidence of diseases caused by lung cancer versus an increased risk of developing lung cancer?

A. I'm sorry. That's a little vague. Can you repeat that?

Q. Okay. Earlier you stated that there's a twenty -- if a person -- let's strike that.

If a person has a smoking history of twenty-pack years, does the prevalence of the incidence of cancer increase at twenty years?

A. I don't know if think you can say the prevalence does. I think the risk is increased.

Q. What do you mean by risk?

A. I mean, the chances in a given poplulation of a hundred people of one of those people developing cancer is increased at twenty years compared to a group of a hundred people that have only smoked, you know, twelve years. But the prevalence doesn't really take that into account. The

prevalence is in the general population; how many people have cancer. That's sort of asking two questions.

The risk goes up after twenty years, but I don't think you can go back and say -- and you can't apply that to prevalence because prevalence that's just a number, that's a statistic.

Q. When people usually talk about twenty years pack history are they talking about the prevalence of the incidence of lung cancer?

A. Well, I'd have to ask that person what they mean, but, in general, I wouldn't say that's prevalence; I'd say that's risk. Again -- and I don't know mean to parse, but that's a definitial thing.

Q. Right. That's why I'm asking.

A. Yeah. The prevalence just is -- in a given population how many people have it, that's prevalence. That has nothing to do with exposures or how old they are. That's just a population of prevalence just is how many people in that population. Not meaning to be professorial.

Q. Right. In your opinion, at what point would a smoker be at an increased risk for developing lung cancer?

A. Scientifically at twenty years that risk becomes -- and I think that's, you know, from my knowledge is the point where that risk becomes significant compared to those who haven't smoked.

Q. What about someone with a five-pack year history?

A. I scientifically really do not experience that risk at five years compared to a non-smoker. There may be a very, very, very small, but for a, you know -- no, that's just -- it's small. The risk factor, I think, it's accepted that at twenty-pack years that risk factor becomes a health issue.

Q. Well, is it correct to state that you did say that a person with a five-pack year history has a higher risk versus a non-smoker of contracting lung cancer?

A. Yeah. And that's a misstatement, and I would say that it's -- and what I was thinking is that I think if you've never smoked, you've got a clean slate. But I think there's this degree, that's this dose-related degree, that I think most people that have smoked five years and quit, wished they had never had. But is their risk any greater? No. I think they're -- if somebody's only smoked five years, quits, or somebody that had smoked five years and they walk in and just ask me what's my scientific opinion; no, they're not in any greater risk than somebody who hadn't smoked at that point.

I think, you know, when you asked the question, that's maybe part of that part

where we were -- my brain doesn't go as fast as your question did.

Q. Well, I'm just confused because I thought now -- let me ask it again.

A. Okay.

Q. My question is: Compared to a never-smoker, does a five-pack year -- person with a five-pack year history have an increased risk of contracting lung cancer compared to that never-smoker?

A. No.

Q. None?

A. None.

MS. KLOK: That's it. I don't have any more questions.

MR. LATHAM: We are done in Birmingham. Anybody else on the phone?

(No response.)

FURTHER SAITH THE DEPONENT NOT.

(The deposition concluded at 12:45 p.m. CST.)

C E R T I F I C A T E

STATE OF ALABAMA)
ETOWAH COUNTY)

I HEREBY CERTIFY that the above and foregoing transcript was taken down by me in stenotype, and the questions and answers thereto were transcribed by means of computer-aided transcription, and that the foregoing represents a true and correct transcript of the testimony given by said witness.

I FURTHER CERTIFY that I am neither of counsel, nor of relation to the parties to the action, nor am I anywise interested in the result of said cause.

_____
CARMEN A. VELEZ
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MY COMMISSION EXPIRES: 2-15-04

DEPONENT'S CERTIFICATE

I, the undersigned, JIMMIE H. HARVEY, M.D.,do hereby certify that I have read the foregoing deposition transcript and that to the best of myknowledge said deposition is true and accurate with the exception of the following correctionslisted below:

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